



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/768,965

02/02/2004

Yuji Nakajima

040040

4559

23850 7590 01/30/2009
KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
Suite 400
WASHINGTON, DC 20005

EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

01/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/768,965 | Applicant(s) NAKAJIMA ET AL. | |
| | Examiner NORA M. ROONEY | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6,9-32,34,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,9-31,34,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 11/17/2008 is acknowledged.
2. Claims 3, 6, 9-31, 34 and 37-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/28/2006 and 04/21/2008.
3. Claim 32 is currently under examination as it reads on an allergen inactivating method for *Dermatophagoides farinae* Hughes allergens by maintaining the allergens under a condition in which an enzyme and a denaturing agent exist, wherein the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain; and the denaturing agent is sodium dodecylsulfate, or urea.
4. In view of the amendments filed on 11/17/2008, only the following rejections are maintained.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1644

6. Claim 32 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons as set forth in the Office Action mailed on 08/19/2008.

Claim 32 recites '*Dermatophagoides farinae* Hughes allergens' and 'the *Pyrococcus furiosus* protease gene.' These terms are indefinite because they only describe the allergen and protease gene of interest by arbitrary names, '*Dermatophagoides farinae* Hughes allergens' and 'the *Pyrococcus furiosus* protease gene.' While the names may have some notion of the specificity of the allergen and protease gene, there is no recitation which distinctly claims them. For example, others in the field may isolate the same allergen and protease gene and give them entirely different names. Applicants should particularly point out and distinctly claim the '*Dermatophagoides farinae* Hughes allergens' and 'the *Pyrococcus furiosus* protease gene' by claiming a sufficient number of characteristics associated with the allergens and protease gene. Claiming biochemical molecules by a particular name given to them by various workers in the field fails to distinctly claim the protein.

Applicant's argument filed on 11/17/2008 has been fully considered, but is not found persuasive.

Applicant argues:

"The rejection of claim 32 is overcome by the amendment to the claim.

The Examiner states that the terms "Df allergens" and "Pfu protease S" are indefinite. Claim 32 has been amended to the term dust mite extract-Df" with "*Dermatophagoides farinae* Hughes." Support for this amendment may be found in the attached document "Mite Extract-Df," which demonstrates that an extract of the dust mite *Dermatophagoides farinae* Hughes is known in the art.

Claim 32 has also been amended to clarify the recitation of "enzyme," by reciting: "wherein the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain." Support for the recitation regarding the *Pyrococcus furiosus* protease gene may be found

Art Unit: 1644

in canceled claim 39, and in the attached document "*Pfu* Protease S." Support for the recitation regarding papain may be found, for example, in claim 31."

It remains the Examiner's position that the recitations of '*Dermatophagoides farinae* Hughes allergens' and 'the *Pyrococcus furiosus* protease gene' in Claim 32 do not distinctly claim the allergen and protease gene. Claiming biochemical molecules by a particular name given to them by various workers in the field fails to distinctly claim the protein. Therefore, Applicant's argument and attached document are not persuasive.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 32 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: an allergen inactivating method for dust mite extract-Df allergens by maintaining the dust mite extract Df-allergens under a condition in which Pfu protease S or papain enzymes and urea or SDS exist, does not reasonably provide enablement for: an allergen inactivating method for ***Dermatophagoides farinae* Hughes allergens** by maintaining the **allergens** under a condition in which **an enzyme** and a denaturing agent exist, wherein **the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene**, or papain; and the denaturing agent is sodium dodecylsulfate, or urea. The specification does not enable any person skilled in the art to which it pertains, or with which

Art Unit: 1644

it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons as set forth in the Office Action mailed on 08/19/2008.

The specification does not adequately disclose an allergen inactivating method for 'Dermatophagoides farinae Hughes allergens.' The specification does not adequately provide support for 'Dermatophagoides farinae Hughes allergens.' Therefore, one of ordinary skill in the art would not be able to practice the claimed method commensurate in scope with the claims without undue experimentation. The claimed Dermatophagoides farinae Hughes allergens read on all Dermatophagoides farinae allergens and derivatives thereof, given that the claims do not recite any specific structure for the allergens. The specification has not adequately disclosed an allergen deactivating method for all Dermatophagoides farinae allergens and derivatives thereof, much less provide adequate guidance on how to make and use the genus of all Dermatophagoides farinae allergens and derivatives thereof in the instantly claimed method.

The specification also does not adequately disclose an allergen inactivating method for *Dermatophagoides farinae* Hughes allergens by maintaining the allergens under a condition in which any 'enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene' exists. The recitation of 'enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene' reads on all enzymes of every *Bacillus* species, including all enzymes of a *Bacillus* species that carries a plasmid that encodes the *Pyrococcus furiosus* protease gene. The instantly recited enzyme is not limited to the *Pyrococcus furiosus* protease. The art teaches that *Bacillus* strains comprise proteases other than 'the *Pyrococcus furiosus* protease': *Bacillus subtilis* comprises keratinase. (PTO-892; Reference U; In particular, abstract, whole document) and *Bacillus licheniformis* comprises organic solvent stable protease

Art Unit: 1644

(PTO-892; Reference V; In particular, abstract, whole document). Further, though it seems that Applicant intends for the term "the *Pyrococcus furiosus* protease" to refer to a specific protein, but the recitation reads on all native and non-native proteases of *Pyrococcus furiosus*. In addition, the art teaches that *Pyrococcus furiosus* comprises the proteases carboxypeptidase (PTO-892; Reference W; In particular, abstract, whole document) and prolidase (PTO-892: Reference X; In particular, abstract, whole document). The specification has not adequately disclosed a method of allergen inactivation using any protease of *Pyrococcus furiosus* or any protease of any *Bacillus* species carrying a plasmid encoding any *Pyrococcus furiosus* protease gene. One of ordinary skill in the art would be required to perform undue experimentation to make and use the instantly claimed allergens and proteases in the instant allergen inactivating method commensurate in scope with the claims.

Applicant's arguments filed on 11/17/2008 have been fully considered, but are not found persuasive.

Applicant argues:

"The rejection of claims 33, 35, 36, 39 and 40 is moot in view of the cancellation of these claims without prejudice or disclaimer. The rejection of claim 32 is overcome by the amendment to the claim.

In Office action paragraph no. 7, the Examiner states that the claims are enabling for "an allergen inactivating method for dust mite extract-Df allergens by maintaining the dust mist extract Df-allergens under a condition in which Pfu protease S or papain enzymes and urea or SDS exist." Claim 32 has been amended to require "an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain" and to require sodium dodecylsulfate (SDS) or urea.

In Office action paragraph no. 8, the Examiner states that Applicant is in possession of: "an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S or papain enzymes and SDS or urea exist." The issue appears to be related to that in paragraph no. 7 of the Office action, and Applicant submits that claim 32 has been amended to be limited in this manner.

It is the Examiner's position that the amendments filed on 11/17/2008 do not overcome the instant rejection. The specification does not adequately disclose an allergen inactivating method for '*Dermatophagoides farinae* Hughes allergens.' The specification does not adequately provide support for '*Dermatophagoides farinae* Hughes allergens.' The specification also does not adequately disclose an allergen inactivating method for *Dermatophagoides farinae* Hughes allergens by maintaining the allergens under a condition in which any 'enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene' exists. The recitation of 'enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene' reads on all enzymes of every *Bacillus* species, including all enzymes of a *Bacillus* species that carries a plasmid that encodes the *Pyrococcus furiosus* protease gene. One of ordinary skill in the art would not be able to practice the claimed method commensurate in scope with the claims without undue experimentation. Therefore, the rejection stands.

9. Claim 32 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention for the same reasons as set forth in the Office Action mailed on 08/19/2008.

Applicant is in possession of: an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S or papain enzymes and SDS or urea exist.

Applicant is not in possession of: an allergen inactivating method for **Dermatophagoides farinae Hughes allergens** by maintaining the **allergens** under a condition in which **an enzyme** and a denaturing agent exist, wherein **the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene**, or papain; and the denaturing agent is sodium dodecylsulfate, or urea.

Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms that are common to the claimed genera. That is, the specification provides neither a representative number of species (allergens, enzymes, proteases,) to describe the claimed genera, nor does it provide a description of structural features that are common to species (allergens, enzymes, proteases) that can be used in the claimed invention. As discussed above, the specification provides no structural description of allergens, enzymes and proteases other than ones specifically exemplified for use in the claimed invention. The specification's disclosure is inadequate to describe the claimed allergen inactivating method using any '*Dermatophagoides farinae* Hughes allergen,' any enzyme or any 'enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene' exists.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be

Art Unit: 1644

satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant's arguments filed on 11/17/2008 have been fully considered, but are not found persuasive.

Applicant argues:

Art Unit: 1644

"The rejection of claims 33, 35, 36, 39 and 40 is moot in view of the cancellation of these claims without prejudice or disclaimer. The rejection of claim 32 is overcome by the amendment to the claim.

In Office action paragraph no. 7, the Examiner states that the claims are enabling for "an allergen inactivating method for dust mite extract-Df allergens by maintaining the dust mite extract Df-allergens under a condition in which Pfu protease S or papain enzymes and urea or SDS exist." Claim 32 has been amended to require "an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain" and to require sodium dodecylsulfate (SDS) or urea.

In Office action paragraph no. 8, the Examiner states that Applicant is in possession of: "an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S or papain enzymes and SDS or urea exist." The issue appears to be related to that in paragraph no. 7 of the Office action, and Applicant submits that claim 32 has been amended to be limited in this manner.

It is the Examiner's position that the specification does not adequately describe structural features of the genus of allergens, enzymes and proteases encompassed by the instant claim recitations. Therefore, the specification does not clearly allow persons of ordinary skill in the art to recognize the genus of methods that have instantly been claimed. Therefore, the rejection stands.

10. The following rejections are necessitated by the amendment filed on 11/17/2008.

11. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a New Matter rejection for the following reasons:

The allergen inactivating method for "*Dermatophagoides farinae* Hughes allergens" using an "enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene" claimed in claim 32 introduced by the amendment filed 11/17/2008 represents a departure from the specification and the claims as originally filed.

Applicant's amendment does not point to the specification for support for the newly added limitations "*Dermatophagoides farinae* Hughes allergens" and "enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene" claimed in claim 32. The specification and the claims as originally filed do not provide a clear support of for "*Dermatophagoides farinae* Hughes allergens" and "enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene."

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1644

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 22, 2009

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/Maher M. Haddad/

Primary Examiner, Art Unit 1644